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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/347,064 07/02/99 ECK

J 09282-5(B352

000570 HM12/1223
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EXAMINER

EWOLDT, G

ART UNIT

PAPER NUMBER

1644

DATE MAILED:

12/23/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action SummaryApplication No.
09/347,064Applicant(s)
Eck et al.Examiner
Gerald EwoldtGroup Art Unit
1644☐ Responsive to communication(s) filed on _____.☐ This action is **FINAL**.☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims☒ Claim(s) 1-46 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.☐ Claim(s) _____ is/are rejected.☐ Claim(s) _____ is/are objected to.☒ Claims 1-46 are subject to restriction or election requirement.**Application Papers**☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.☐ The drawing(s) filed on _____ is/are objected to by the Examiner.☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.☐ The specification is objected to by the Examiner.☐ The oath or declaration is objected to by the Examiner.**Priority under 35 U.S.C. § 119**☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.☐ received in Application No. (Series Code/Serial Number) _____.☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).**Attachment(s)**☐ Notice of References Cited, PTO-892☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____☐ Interview Summary, PTO-413☐ Notice of Draftsperson's Patent Drawing Review, PTO-948☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-27, 29, and 32-37 drawn to nucleic acids encoding a fusion protein, a host, and a process of producing a fusion protein, classified in Class 536, subclass 23.4 and Class 435, subclasses 69.1, 252.3, and 320.1.

II. Claims 28 and 30-32, drawn to a fusion protein and a medicament, classified in Class 424, subclass 192.1 and Class 530, subclass 350.

III. Claims 38-42, drawn to a method of modulating intracellular toxins, classified in Class 424, subclass 192.1.

IV. Claims 43-46, drawn to a process of *in vitro* testing of cellular modulators, classified in Class 453, subclass 6.

The inventions are distinct, each from the other because:

2. Inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)).

In the instant case, the product as claimed can be used in a materially different process such as an immunogen or for immunopurification.

3. Inventions I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)).

In the instant case, the product as claimed can be used in a materially different process such as nucleic acid blots or as *in vivo* vectors.

4. Inventions III and IV are different processes. These inventions require different ingredients, process steps and endpoints. Therefore they are patentably distinct.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

6. Irrespective of whichever Group Applicant should elect, Applicant is further required under 35 U.S.C. § 121 to:

1) Elect:

A) A **specific** embodiment of an effector module; a **specific** embodiment of a processing module; and a **specific** embodiment of a targeting module. If an embodiment including a modulating or modulating plus affinity module is chosen, a **specific** modulating or **specific** modulating plus **specific** affinity module (Group I).

B) A **specific** embodiment of an effector module; a **specific** embodiment of a processing module; and a **specific** embodiment of a targeting module. If an embodiment including a modulating module is chosen, a **specific** modulating module (Group II).

C) A **specific** embodiment of an effector module; a **specific** embodiment of a processing module; and a **specific** embodiment of a targeting module. If an embodiment including a modulating plus affinity module is chosen, a **specific** modulating plus **specific** affinity module (Group III).

D) A **specific** embodiment of an effector module; a **specific** embodiment of a processing module; a **specific** embodiment of a targeting module, and a **specific** modulating module (Group IV).

2) List all Claims readable thereon including those subsequently added. Currently Claims 1, 11-12, and 20 are generic.

7. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The different modules, and combinations of modules, confer entirely different functions and specificities to the fusion proteins and medicaments. Therefore, the species of Groups I, II, III, and IV are independent patentable over one another.

8. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

10. A telephone call was made to Gary Colby on 12/13/99 to request an oral election to the above restriction requirement, but did not result in an election being made. A written restriction was requested.

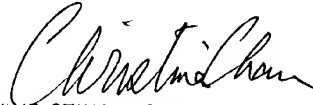
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Art Unit 1644

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11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CMI Fax Center telephone number is (703) 305-3014.

Gerald Ewoldt, Ph.D.
Patent Examiner
Group 1640
Technology Center 1600
December 13, 1999


CHRISTINA Y. CHAN
SUPERVISORY PATENT EXAMINER
GROUP 1600 1640